

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#8

Applicants: Suzanne Cory, et al.

Serial No.: 09/508,745

Filed: July 12, 2000

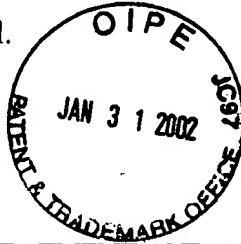
For: A METHOD OF TREATMENT AND AN ANIMAL MODEL USEFUL FOR SAME

Examiner: Sumesh Kaushal

Art Unit: 1633

Docket: 13464

Dated: October 26, 2001



TECH CENTER 1600/2900

FEB 04 2002

RECEIVED

Assistant Commissioner for Patents
Washington, D.C. 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, it is requested that the following references, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

1. Tsujimoto, et al., "Involvement of the *bcl-2* Gene in Human Follicular Lymphoma", Science 228: 1440-1443 (1985);
2. Kerr, J.F.R. et al., "Apoptosis: A Basic Biological Phenomenon with Wide-Ranging Implications in Tissue Kinetics", Br. J. Cancer 26: 239-257 (1972);
3. Strasser, A. et al., "The Role of the *bcl-2* / *ced-9* Gene Family in Cancer and General Implications of Defects in Cell Death Control for Tumourigenesis and Resistance to Chemotherapy", Biochimica et Biophysica Acta F151-F178 (1997);

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on October 26, 2001.

Dated: October 26, 2001

Michelle Mustafa

4. Adams, J.M. et al., "The Bcl-2 Protein Family: Arbiters of Cell Survival", Science **281**: 1322-1326 (1998);
5. Chao, D.T. et al., "Bcl-2 Family: Regulators of Cell Death", Annu. Rev. Immunol **16**: 395-419 (1998);
6. Oltvai, Z.N. et al., "Bcl-2 Heterodimerizes In Vivo with a Conserved Homolog, Bax, that Accelerates Programed Cell Death", Cell **74**: 609-619 (1993);
7. Pan, G. et al., "Caspase-9, Bcl-X_L, and Apaf-1 Form a Ternary Complex", The Journal of Biological Chemistry **273**(10): 5841-5845 (1998);
8. Chinnaiyan, A.M. et al., "Interaction of CED-4 with CED-3 and CED-9: A Molecular Framework for Cell Death", Science **275**: 1122-1126 (1997);
9. Susin, S.A. et al., "Bcl-2 Inhibits the Mitochondrial Release of an Apoptogenic Protease", J. Exp. Med. **184**: 1331-1341 (1996);
10. Yang, J. et al., "Prevention of Apoptosis by Bcl-2: Release of Cytochrome c from Mitochondria Blocked", Science **275**: 1129-1132 (1997);
11. Kluck, R.M. et al., "The Release of Cytochrome c from Mitochondria: A Primary Site for Bcl-2 Regulation of Apoptosis", Science **275**: 1132-1136 (1997);
12. Veis, D.J. et al., "Bcl-2-Deficient Mice Demonstrate Fulminant Lymphoid Apoptosis, Polycystic Kidneys, and Hypopigmented Hair", Cell **75**: 229-240 (1993);
13. Kamada, S. et al., "Bcl-2 Deficiency in Mice Leads to Pleiotropic Abnormalities: Accelerated Lymphoid Cell Death in Thymus and Spleen, Polycystic Kidney, Hair Hypopigmentation, and Distorted Small Intestine", Cancer Research **55**: 354-359 (1995);
14. Nakayama, K. et al., "Disappearance of the Lymphoid System in Bcl-2 Homozygous Mutant Chimeric Mice", Science **261**: 1584-1588 (1993);
15. Nakayama, K. et al., "Targeted Disruption of Bcl-2 $\alpha\beta$ in Mice: Occurrence of Gray Hair, Polycystic Kidney Disease, and Lymphocytopenia", Proc. Natl. Acad. Sci. USA **91**: 3700-3704 (1994);
16. Amling, M. et al., "Bcl-2 Lies Downstream of Parathyroid Hormone-Related Peptide in a Signaling Pathway that Regulates Chondrocyte Maturation During Skeletal Development", The Journal of Cell Biology **136**(1): 205-213 (1997);


17. Michaelidis, T.M. et al., "Inactivation of *bcl-2* Results in Progressive Degeneration of Motoneurons, Sympathetic and Sensory Neurons During Early Postnatal Development", Neuron **17**: 75-89 (1996);
18. Motoyama, N. et al., "Massive Cell Death of Immature Hematopoietic Cells and Neurons in Bcl-x-Deficient Mice", Science **267**: 1506-1510 (1995);
19. Needleman, S.B. et al., "A General Method Applicable to the Search for Similarities in the Amino Acid Sequence of Two Proteins", J. Mol. Biol. **48**: 443-453 (1970);
20. Lou, D. et al., "Enhanced Molecular Mimicry of CEA Using Photoaffinity Crosslinked C3d Peptide", Nature Biotechnology **16**: 458-462 (1998);
21. Boyle, J.S. et al., "Enhanced Responses to a DNA Vaccine Encoding a Fusion Antigen that is Directed to Sites of Immune Induction", Nature **392**: 408-411 (1998);
22. Lane, P. et al., "Soluble CD40 Ligand Can Replace the Normal T Cell-Derived CD40 Ligand Signal to B Cells in T Cell-Dependent Activation", J. Exp. Med. **177**: 1209-1213 (1993);
23. Köntgen, F. et al., "Mice Lacking the *c-rel* Proto-Oncogene Exhibit Defects in Lymphocyte Proliferation, Humoral Immunity, and Interleukin-2 Expression", Genes & Development **9**: 1965-1977 (1995);
24. Mansour, S.L. et al., "Disruption of the Proto-Oncogene *int-2* in Mouse Embryo-Derived Stem Cells: A General Strategy for Targeting Mutations to Non-Selectable Genes", Nature **336**: 348-352 (1988);
25. Lakso, M. et al., "Efficient *in vivo* Manipulation of Mouse Genomic Sequences at the Zygote Stage", Proc. Natl. Acad. Sci. USA **93**: 5860-5865 (1996);
26. Hudson, D., "Fitting Segmented Curves Whose Join Points Have to be Estimated", J. Am. Stat. Assoc. **61**: 1097-1129 (1966);
27. Chomczynski, P. et al., "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction", Analytical Biochemistry **162**: 156-159 (1987);
28. Gorczyca, et al., "Detection of DNA Strand Breaks in Individual Apoptotic Cells by the *in Situ* Terminal Deoxynucleotidyl Transferase and Nick Translation Assays", Cancer Research **53**: 1945-1951 (1993);
29. Unkeless, J.C., "Characterization of a Monoclonal Antibody Directed Against Mouse Macrophage and Lymphocyte Fc Receptors", J. Exp. Med. **150**: 580-596 (1979);

30. Strasser, A. et al., "Bcl-2 Transgene Inhibits T Cell Death and Perturbs Thymic Self-Censorship", Cell **67**: 889-899 (1991);
31. Metcalf, D. et al., The Hemopoietic Colony-Stimulating Factors (Elsevier Science Publications, Amsterdam);
32. Wreford, N.G., "Theory and Practice of Stereological Techniques Applied to the Estimation of Cell Number and Nuclear Volume in the Testis", Microscopy Research and Technique **32**: 423-436 (1995);
33. Meinhardt, A. et al., "Localization of Follistatin in the Rat Testis", Journal of Reproduction and Fertility **112**: 233-241 (1998);
34. Lee, V.W.K. et al., "Variations in Serum FSH, LH and Testosterone Levels in Male Rats from Birth to Sexual Maturity", Journal of Reproduction and Fertility **42**: 121-126 (1975);
35. Lee, et al., "Genomic Structure and Expression of Murine Poly (A) Binding Protein II Gene", Biochimica et Biophysica Acta **1395**: 40-46 (1998); and
36. O'Connor, L. et al., "Bim: A Novel Member of the Bcl-2 Family that Promotes Apoptosis", The EMBO Journal **17(2)**: 384-395 (1998).

Applicants are submitting copies of the above-cited references.

Inasmuch as this Information Disclosure Statement is being submitted in accordance with the schedule set out in 37 C.F.R. § 1.97(b), no statement or fee is required.

Respectfully submitted,



Frank S. DiGiglio
Registration No. 31,346

Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343

FSD/XZ:dg

1633

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

(Under 37 CFR 1.97(b) of P. 27(c))

Docket No.

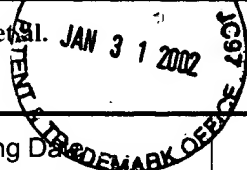
13464

TECH CENTER 1500/2900

FEB 04 2002

RECEIVED

In Re Application Of: Suzanne C ry, et al.



Serial No.

09/508,745

Filing Date

July 12, 2000

Examiner

Sumesh Kaushal

Group Art

1633

Title:

A METHOD OF TREATMENT AND AN ANIMAL MODEL USEFUL FOR SAME

Address to:

Assistant Commissioner for Patents

Washington, D.C. 20231

37 CFR 1.97(b)

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application; within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; or before the mailing date of a first Office Action on the merits, whichever event occurs last.

37 CFR 1.97(c)

2. ☐ The Information Disclosure Statement submitted herewith is being filed after three months of the filing of a national application, or the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; or after the mailing date of a first Office Action on the merits, whichever occurred last but before the mailing date of either:

1. a Final Action under 37 CFR 1.113, or
 2. a Notice of Allowance under 37 CFR 1.311,
- whichever occurs first.

Also submitted herewith is:

- ☐ a certification as specified in 37 CFR 1.97(e);

OR

- ☐ the fee set forth in 37 CFR 1.17(p) for submission of an Information Disclosure Statement under 37 CFR 1.97(c).

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) of 1.97(e))

Docket No.
13464

In Re Application Of: Suzanne Cory, et al.

JAN 31 2002

Serial No.
09/508,745

Filing Date
July 12, 2000

Examiner
Sumesh Kaushal

Group Art Unit
1633

Title:

A METHOD OF TREATMENT AND AN ANIMAL MODEL USEFUL FOR SAME

Payment of Fee

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of _____ is attached.
- ☒ The Assistant Commissioner is hereby authorized to charge and credit Deposit Account No. 19-1013/SSMP as described below. A duplicate copy of this sheet is enclosed.
- ☐ Charge the amount of _____
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.

Certificate of Transmission by Facsimile*

I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (Fax No. _____) on _____ (Date).

Signature

Typed or Printed Name of Person Signing Certificate

Certificate of Mailing by First Class Mail

I certify that this document and fee is being deposited on **October 26, 2001** with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Signature of Person Mailing Correspondence

Michelle Mustafa

Typed or Printed Name of Person Mailing Correspondence

*This certificate may only be used if paying by deposit account.

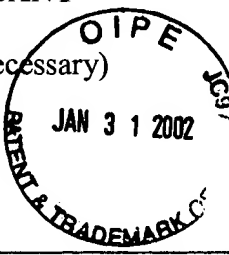

Signature

Dated: October 26, 2001

Frank S. DiGiglio
Registration No. 31,346
SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza
Garden City, NY 11530
(516) 742-4343

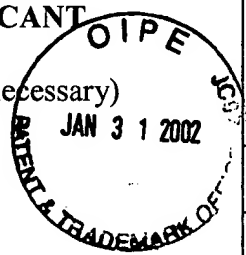
FSD/XZ:dg

cc:

Form PTO-1449 U.S. DEPARTMENT OF COMMERCE (REV. 7-80) PATENT AND TRADEMARK OFFICE LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)		Atty. Docket No. 13464		Serial No. 09/508,745			
		Applicant Suzanne Cory, et al.		<div style="writing-mode: vertical-rl; transform: rotate(180deg);"> RECEIVED FEB 04 2002 TECH CENTER 1600/2900 </div>			
		Filing Date July 12, 2000				Group Art Unit 1633	
U.S. PATENT DOCUMENTS							
EXAMINE R INITIAL*		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (if appropriate)
	AA						
	AB						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
OTHER DOCUMENTS							
(Including Author, Title, Date, Pertinent Pages, Etc.)							
		Tsujimoto, et al., "Involvement of the <i>bcl-2</i> Gene in Human Follicular Lymphoma", <u>Science</u> 228: 1440-1443 (1985)					
		Kerr, J.F.R. et al., "Apoptosis: A Basic Biological Phenomenon with Wide-Ranging Implications in Tissue Kinetics", <u>Br. J. Cancer</u> 26: 239-257 (1972)					
		Strasser, A. et al., "The Role of the <i>bcl-2</i> / <i>ced-9</i> Gene Family in Cancer and General Implications of Defects in Cell Death Control for Tumourigenesis and Resistance to Chemotherapy", <u>Biochimica et Biophysica Acta</u> F151-F178 (1997)					
		Adams, J.M. et al., "The Bcl-2 Protein Family: Arbiters of Cell Survival", <u>Science</u> 281: 1322-1326 (1998)					
		Chao, D.T. et al., "Bcl-2 Family: Regulators of Cell Death", <u>Annu. Rev. Immunol</u> 16: 395-419 (1998)					
		Oltvai, Z.N. et al., "Bcl-2 Heterodimerizes In Vivo with a Conserved Homolog, Bax, that Accelerates Programed Cell Death", <u>Cell</u> 74: 609-619 (1993)					
		Pan, G. et al., "Caspase-9, Bcl-X _L , and Apaf-1 Form a Ternary Complex", <u>The Journal of Biological Chemistry</u> 273(10): 5841-5845 (1998)					
		Chinnaiyan, A.M. et al., "Interaction of CED-4 with CED-3 and CED-9: A Molecular Framework for Cell Death", <u>Science</u> 275: 1122-1126 (1997)					
		Susin, S.A. et al., "Bcl-2 Inhibits the Mitochondrial Release of an Apoptogenic Protease", <u>J. Exp. Med.</u> 184: 1331-1341 (1996)					
		Yang, J. et al., "Prevention of Apoptosis by Bcl-2: Release of Cytochrome c from Mitochondria Blocked", <u>Science</u> 275: 1129-1132 (1997)					
		Kluck, R.M. et al., "The Release of Cytochrome c from Mitochondria: A Primary Site for Bcl-2 Regulation of Apoptosis", <u>Science</u> 275: 1132-1136 (1997)					
		Veis, D.J. et al., "Bcl-2-Deficient Mice Demonstrate Fulminant Lymphoid Apoptosis, Polycystic Kidneys, and Hypopigmented Hair", <u>Cell</u> 75: 229-240 (1993)					
EXAMINER				DATE CONSIDERED			
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

RECEIVED
FEB 04 2002
TECH CENTER 1600/2900

Form PTO-1449 (REV. 7-80) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		Atty. Docket No. 13464	Serial No. 09/508,745
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)		Applicant Suzanne Cory, et al.	
		Filing Date July 12, 2000	Group Art Unit 1633



U.S. PATENT DOCUMENTS

EXAMINE R INITIAL*		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (if appropriate)
	AA						
	AB						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

		Kamada, S. et al., "Bcl-2 Deficiency in Mice Leads to Pleiotropic Abnormalities: Accelerated Lymphoid Cell Death in Thymus and Spleen, Polycystic Kidney, Hair Hypopigmentation, and Distorted Small Intestine", <u>Cancer Research</u> 55: 354-359 (1995)
		Nakayama, K. et al., "Disappearance of the Lymphoid System in Bcl-2 Homozygous Mutant Chimeric Mice", <u>Science</u> 261: 1584-1588 (1993)
		Nakayama, K. et al., "Targeted Disruption of Bcl-2aβ in Mice: Occurrence of Gray Hair, Polycystic Kidney Disease, and Lymphocytopenia", <u>Proc. Natl. Acad. Sci. USA</u> 91: 3700-3704 (1994)
		Amling, M. et al., "Bcl-2 Lies Downstream of Parathyroid Hormone-Related Peptide in a Signaling Pathway that Regulates Chondrocyte Maturation During Skeletal Development", <u>The Journal of Cell Biology</u> 136(1): 205-213 (1997)
		Michaelidis, T.M. et al., "Inactivation of bcl-2 Results in Progressive Degeneration of Motoneurons, Sympathetic and Sensory Neurons During Early Postnatal Development", <u>Neuron</u> 17: 75-89 (1996)
		Motoyama, N. et al., "Massive Cell Death of Immature Hematopoietic Cells and Neurons in Bcl-x-Deficient Mice", <u>Science</u> 267: 1506-1510 (1995)
		Needleman, S.B. et al., "A General Method Applicable to the Search for Similarities in the Amino Acid Sequence of Two Proteins", <u>J. Mol. Biol.</u> 48: 443-453 (1970)
		Lou, D. et al., "Enhanced Molecular Mimicry of CEA Using Photoaffinity Crosslinked C3d Peptide", <u>Nature Biotechnology</u> 16: 458-462 (1998)
		Boyle, J.S. et al., "Enhanced Responses to a DNA Vaccine Encoding a Fusion Antigen that is Directed to Sites of Immune Induction", <u>Nature</u> 392: 408-411 (1998)
		Lane, P. et al., "Soluble CD40 Ligand Can Replace the Normal T Cell-Derived CD40 Ligand Signal to B Cells in T Cell-Dependent Activation", <u>J. Exp. Med.</u> 177: 1209-1213 (1993)

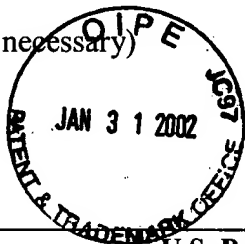
EXAMINER	DATE CONSIDERED
----------	-----------------

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. DEPARTMENT OF COMMERCE
(REV. 7-80) PATENT AND TRADEMARK OFFICE

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)



Atty. Docket No.

13464

Serial No.

09/508,745

Applicant

Suzanne Cory, et al.

Filing Date

July 12, 2000

Group Art Unit

1633

U.S. PATENT DOCUMENTS

EXAMINE R INITIAL*	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (if appropriate)
AA						
AB						

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
					YES NO

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

	Köntgen, F. et al., "Mice Lacking the c-rel Proto-Oncogene Exhibit Defects in Lymphocyte Proliferation, Humoral Immunity, and Interleukin-2 Expression", <u>Genes & Development</u> 9: 1965-1977 (1995)
	Mansour, S.L. et al., "Disruption of the Proto-Oncogene int-2 in Mouse Embryo-Derived Stem Cells: A General Strategy for Targeting Mutations to Non-Selectable Genes", <u>Nature</u> 336: 348-352 (1988)
	Lakso, M. et al., "Efficient <i>in vivo</i> Manipulation of Mouse Genomic Sequences at the Zygote Stage", <u>Proc. Natl. Acad. Sci. USA</u> 93: 5860-5865 (1996)
	Hudson, D., "Fitting Segmented Curves Whose Join Points Have to be Estimated", <u>J. Am. Stat. Assoc.</u> 61: 1097-1129 (1966)
	Chomczynski, P. et al., "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction", <u>Analytical Biochemistry</u> 162: 156-159 (1987)
	Gorczyca, et al., "Detection of DNA Strand Breaks in Individual Apoptotic Cells by the <i>in Situ</i> Terminal Deoxynucleotidyl Transferase and Nick Translation Assays", <u>Cancer Research</u> 53: 1945-1951 (1993)
	Unkeless, J.C., "Characterization of a Monoclonal Antibody Directed Against Mouse Macrophage and Lymphocyte Fc Receptors", <u>J. Exp. Med.</u> 150: 580-596 (1979)
	Strasser, A. et al., "Bcl-2 Transgene Inhibits T Cell Death and Perturbs Thymic Self-Censorship", <u>Cell</u> 67: 889-899 (1991)
	Metcalf, D. et al., <u>The Hemopoietic Colony-Stimulating Factors</u> (Elsevier Science Publications, Amsterdam)
	Wreford, N.G., "Theory and Practice of Stereological Techniques Applied to the Estimation of Cell Number and Nuclear Volume in the Testis", <u>Microscopy Research and Technique</u> 32: 423-436 (1995)
	Meinhardt, A. et al., "Localization of Follistatin in the Rat Testis", <u>Journal of Reproduction and Fertility</u> 112: 233-241 (1998)

EXAMINER

DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

(Use several sheets if necessary)

BY APPLICANT
al sheets if necessary
JAN 31 2002
COPYRIGHT & TRADEMARK OFFICE

13464

09/508,745

Filing Date
July 12, 2000

Group Art Unit
1633

RECEIVED
FEB 04 2002
TECH CENTER 1600/2900

EXAMINE R INITIAL*		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (if appropriate)
	AA						
	AB						

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

(Including Author, Title, Date, Pertinent Pages, Etc.)

O'Connor, L. et al., "Bim: A Novel Member of the Bcl-2 Family that Promotes Apoptosis", The EMBO Journal 17(2): 384-395 (1998)

DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.